

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference ML/P32320	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/02107	International filing date (day/month/year) 01/06/2000	Priority date (day/month/year) 01/06/1999
International Patent Classification (IPC) or national classification and IPC A61K38/00		
Applicant SmithKline Beecham plc		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input checked="" type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 13/12/2000	Date of completion of this report 27.02.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Deck, A Telephone No. +49 89 2399 8432	



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02107

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-29 as originally filed

Claims, No.:

1-13 as originally filed

Sequence listing part of the description, pages:

29, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/02107

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-13
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-13
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/02107

Concerning section V:

The present invention claims the further medical use of h-TREK1 polypeptide or polynucleotide, activators, inhibitors for the manufacture of a medicament for treating neurological diseases.

The available prior art neither describes nor suggests such use, therefore the present application seems to meet the requirements of Article 33(2), (3) and (4) PCT.

Concerning section VI:

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-9937762	29.07.99	02.13.98	27.01.98

The priority dates of this document have been checked as being validly claimed.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ML/P32320	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/02107	International filing date (day/month/year) 01/06/2000	(Earliest) Priority Date (day/month/year) 01/06/1999
Applicant SmithKline Beecham plc		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

USES OF H-TREK-1 POLYPEPTIDES AND POLYNUCLEOTIDES ENCODING THEM

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-6 (partially), 9, 10

Present claims 1-6 (partially), 9 and 10 relate to compounds defined by reference to a desirable characteristic or property, namely inhibition or activation of h-TREK-1.

The claims cover all compounds having this property, whereas the application provides no support within the meaning of Article 6 PCT or disclosure within the meaning of Article 5 PCT for any such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compounds by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to h-TREK-1 and polynucleotides encoding it.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/02107

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K38/17 A61P13/00 A61P15/10 A61P17/14 A61P25/08
A61P25/14 A61P25/22 A61P25/28 A61P25/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, BIOSIS, WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 99 37762 A (SMITHKLINE BEECHAM PLC) 29 July 1999 (1999-07-29) cited in the application page 1, line 20 - line 30; claim 16; example 1	1-13
A	--- M. FINK ET AL.: "Cloning, functional expression and brain localization of a novel unconventional outward rectifier K+ channel" THE EMBO JOURNAL, vol. 15, no. 24, 1996, pages 6854-6862, XP002085602 page 6860, column 1, paragraph 3 -column 2, paragraph 1 -----	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

11 December 2000

Date of mailing of the international search report

18/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Skelly, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/02107

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9937762 A	29-07-1999	EP 1051485 A	15-11-2000

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 December 2000 (07.12.2000)

PCT

(10) International Publication Number
WO 00/72863 A3

(51) International Patent Classification⁷: **A61K 38/17**,
A61P 13/00, 15/10, 17/14, 25/08, 25/14, 25/22, 25/28,
25/30

(74) Agent: **CONNELL, Anthony, Christopher**; SmithKline
Beecham, Two New Horizons Court, Brentford, Middlesex
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(21) International Application Number: **PCT/GB00/02107**

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE,
DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU,
ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS,
LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO,
NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR,
TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(22) International Filing Date: **1 June 2000 (01.06.2000)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
9912733.4 **1 June 1999 (01.06.1999)** **GB**

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*):
SMITHKLINE BEECHAM PLC [GB/GB]; New
Horizons Court, Brentford, Middlesex TW8 9EP (GB).

Published:

- *With international search report.*
- *Before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments.*

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **HERVIEU, Guil-**
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Harlow, Essex CM19 5AW (GB). **MEADOWS, Helen,**
Jane [GB/GB]; SmithKline Beecham Pharmaceuticals,
New Frontiers Science Park South, Third Avenue, Harlow,
Essex CM19 5AW (GB). **RANDALL, Andrew, David**
[GB/GB]; SmithKline Beecham Pharmaceuticals, New
Frontiers Science Park South, Third Avenue, Harlow,
Essex CM19 5AW (GB).

(88) Date of publication of the international search report:
22 February 2001

*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: **USES OF H-TREK-1 POLYPEPTIDES AND POLYNUCLEOTIDES ENCODING THEM**

(57) Abstract: The use of h-TREK1 polypeptides and polynucleotides in the design of protocols for the treatment of epilepsy, sleep-related disorders, the induction of sleep, cognitive dysfunction/enhancement, attention deficit disorder, addiction, anxiety/phobia, dyskinesias including Parkinson's and Huntington's chorea, Cerebral palsy, incontinence, erectile dysfunction, alopecia, among others, and diagnostic assays for such conditions. Also disclosed are methods for producing such polypeptides by recombinant techniques.

WO 00/72863 A3



INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/GB 00/02107

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K38/17 A61P13/00 A61P15/10 A61P17/14 A61P25/08
A61P25/14 A61P25/22 A61P25/28 A61P25/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, BIOSIS, WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	M. FINK ET AL.: "Cloning, functional expression and brain localization of a novel unconventional outward rectifier K ⁺ channel" THE EMBO JOURNAL, vol. 15, no. 24, 1996, pages 6854-6862, XP002085602 page 6860, column 1, paragraph 3 -column 2, paragraph 1	1



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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

11 December 2000

Date of mailing of the international search report

18/12/2000

Name and mailing address of the ISA

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FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Claims Nos.: 1-6 (partially), 9, 10

Present claims 1-6 (partially), 9 and 10 relate to compounds defined by reference to a desirable characteristic or property, namely inhibition or activation of h-TREK-1.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/02107

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9937762 A	29-07-1999	EP 1051485 A	15-11-2000